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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,247	02/14/2002	Paul A. Wender	8400-0013	3262
<div>23980      7590      05/29/2007</div> <div>MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C</div> <div>1400 PAGE MILL ROAD</div> <div>PALO ALTO, CA 94304-1124</div>				
			<div>EXAMINER</div> <div>GUDIBANDE, SATYANARAYAN R</div>	
			<div>ART UNIT</div> <div>1654</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>05/29/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/078,247

Applicant(s)

WENDER ET AL.

Examiner

Satyanarayana R. Gudibande

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,9,10 and 12-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 8 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/8/07 has been entered.

Applicant's amendments to claims in the response filed on 3/8/07 have been acknowledged.

Claims 1-6 and 8-35 are pending.

Claims 3, 5, 6, 9, 10 and 12-35 have been withdrawn from further consideration as being drawn to non-elected species.

Claim 7 has been canceled.

Claims 1, 2, 4, 8 and 11 are examined on the merit.

Any objections and rejections not specifically mentioned here is considered withdrawn.

### ***Claim Objections***

Claim 11 contains allowable subject matter but depends from a rejected claim 4.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112 First Paragraph***

Applicant's arguments and amendments to claims, see page 13, filed 3/8/07, with respect to claim rejection under 35 USC 112 first paragraph, have been fully considered and are persuasive. The rejection of claims 1, 2, 4, 8 and 11 has been withdrawn.

***Maintained Rejections***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lorezen, et al., The Journal of Cell Biology, 1995, 131, 631-643 as stated in our rejection dated 9/21/06 for claims 1, 2, 7 and 8.

Applicants argue that the claims have been currently amended creating another distinction between the cited reference of Lorezen and the instant application. Applicants state that the inclusion of the phrase, “and a linker capable of self-immolation linking the biologically active compound and the transport moiety” is not described or implied in Lorezen. Applicants further argue that Lorezen teaches a peptide as part of a test peptide encoding a detectable marker protein and an amino acid sequence that includes TCPCP. The test peptide localizes to the nuclear membrane of a cell, where the marker is transcribed and translated in the cytoplasm.

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By deletion analysis, Lorenzen claims that a downstream RKRR sequence localizes the peptide to the nuclear membrane. However, this does not anticipate instant claims 1 or 2. In the instant claims, there are three separate regions that are **covalently joined together** (emphasis added by Examiner): (1) the biologically active compound, that is (2) linked by a linker, to (3) the transport region. Not only is there is no linker between the region that can optionally be RKRR and the expressed marker region of the Lorenzen test peptide, there is no non-amino acid, self immolating linking moiety. The currently claimed invention provides the user the benefit of taking three separate elements, as noted above, and bringing them together to **create a conjugate** (emphasis added by Examiner) that can increase the amount of biologically active compound that can pass through a biological membrane, such as a cellular membrane. After passage of the conjugate through a biological membrane, the linker self-immolates, leaving a peptidyl transporter and the desired biologically active compound. Because anticipation requires the presence of all elements in the anticipating art, Lorenzen does not anticipate claims 1, 2 or 8.

Applicant's arguments filed 3/8/07 have been fully considered but they are not persuasive. Because, as stated in our previous office action dated 9/21/06, that the claims are drawn to "A composition comprising of...", and therefore, allows additional proteins and other substance to be present in the composition. Applicants argue that now the claims have been amended and recite the phrase, "and a linker capable of self-immolation linking the biologically active compound and the transport moiety" it precludes the cited reference from anticipation of the instant claims. Applicants, further state that the three separate regions are **covalently joined together** (emphasis added by Examiner): (1) the biologically active compound, that is (2) linked

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by a linker, to (3) the transport region. In the cited reference of Lorenzen, et al., in figure 1 on page 633, we have the schematic diagram of the TCPTP. The schematic diagram depicts the catalytic region in black (biologically active moiety of the instant invention) coupled to the intron region represented by diagonal lines (linker of the instant application) to the non-catalytic region represented by the open area that contains the RKRKR moiety which is a part of nuclear localization signal (transport moiety). Moreover, the claim as recited in the instant application does not recite a conjugate wherein the transport moiety, linker and biologically active moieties are linked to one another by covalent linkage, but, the claims are drawn to, **“A composition comprising** a biologically active compound, a transport moiety and a linker capable of self-immolation linking the biologically active compound and a transport moiety”. Therefore, the claims as recited are anticipated by the cited reference of Lorenzen and hence the anticipation rejection is maintained.

Claims 1 and 4 remain rejected under 35 U.S.C. 102(b) as being anticipated by Olsson et al., *Biochim. Biophys. Acta*, 1991, 1097:37-44 as stated in our rejection dated 9/21/06 for claims 1 and 4.

Applicants argue that Olsson does not teach all of the elements of the instant claims. Olsson lacks a teaching of a covalently bound linker between the transport moiety and a biologically active compound, let alone a teaching of a self-immolating linker. In fact, the arginine-serine region taught by Olsson is not bound at all to the biologically active compound. Instead, it is used in a competition-binding assay.

Applicant's arguments filed 3/8/07 have been fully considered but they are not persuasive. Because, as stated in our previous office action dated 9/21/06, that the claims are drawn to "A composition comprising of...", and therefore, allows additional proteins and other substance to be present in the composition. Claim as recited does not recite a conjugate wherein the transport moiety, linker and biologically active moieties are linked to one another by covalent linkage. Again, the claims are drawn to, "A composition comprising a biologically active compound, a transport moiety and a linker capable of self-immolation linking the biologically active compound and a transport moiety". Therefore, the claims as recited are anticipated by the cited reference of Olsson and hence the anticipation rejection is maintained.

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4 and 8 remain rejected under 35 U.S.C. 102(e) as being anticipated by US 7,070,807 B2 issued to Mixson as stated in our rejection dated 9/21/06 for claims 1, 2, 4, 7 and 8.

Applicants argue that as with other references used in 102(b) rejection, Mixson does not teach a self-immolating linker.

Applicant's arguments filed 3/8/07 have been fully considered but they are not persuasive. Because, as stated in our previous office action dated 9/21/06, that the claims are drawn to "A composition comprising of...", and therefore, allows additional proteins and other substance to be present in the composition. Claim as recited does not recite a conjugate wherein

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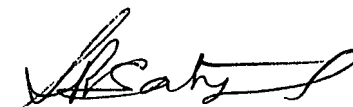
the transport moiety, linker and biologically active moieties are linked to one another by covalent linkage. Again, the claims are drawn to, "A composition comprising a biologically active compound, a transport moiety and a linker capable of self-immolation linking the biologically active compound and a transport moiety". Therefore, the claims as recited are anticipated by the cited reference of Mixson and hence the anticipation rejection is maintained.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Satyanarayana R. Gudibande, Ph.D.  
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**ANISH GUPTA**  
**PRIMARY EXAMINER**